REMARKS

Claim Rejections – 35 USC §103

Claims 16-19 and 21-26 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,083,225 to Winslow et al. in view of U.S. Patent No. 4,862,891 to Smith and U.S. Patent Application Publication No. 2002/0002360 to Orth et al.

It is well established that "[t]o establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure." MPEP §2142 (citing In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)).

As an initial matter, the Applicant notes that independent claim 34 has been rewritten to depend from independent claim 21.

Independent claim 16 is directed to "a surgical kit for performing percutaneous interbody fusion" and recites, among other elements and features, "at least one intervertebral disc spacer" configured for insertion into an intervertebral disc space, at least one guide needle, "a plurality of dilators sized and configured to incrementally increase a height of the intervertebral disc space", with "each dilator having an inner diameter successively larger than an outer diameter of a previous dilator such that a distal end portion of each dilator is positioned within the intervertebral disc space to incrementally increase a height of the intervertebral disc space", and packaging for containing the recited components in a sterilized condition. Similarly, independent claim 21 is directed to "a surgical kit for implantation of a spinal implant into an intervertebral disc space" and recites, among other elements and features, "at least one spinal implant" configured for insertion into the intervertebral disc space, "a plurality of dilators sized and configured to incrementally increase a height of the intervertebral disc space", including "a

first dilator having an outer diameter and a distal end portion sized for insertion into the intervertebral disc space [and] a second dilator having an inner diameter sized larger than an outer diameter of the first dilator to allow passage of the second dilator over the first dilator until a distal end portion of the second dilator is positioned within the intervertebral disc space to incrementally increase a height of the intervertebral disc space".

As set forth on pages 2 and 3 of the Office Action, an assertion is made that Winslow discloses "at least one intervertebral disc spacer that is configured for insertion into an intervertebral disc . . . A retractor is used for delivering the at least one disc spacer through one of the dilators to an intervertebral disc space". However, the Office Action admits that Winslow fails to disclose "at least one guide needle and a plurality of dilators [and] a package that is sterilized with the claimed instrumentation". Nevertheless, the Office Action asserts that "Smith discloses at least one guide needle (33) and a plurality of dilators (36-41) . . . each dilator having an inner diameter successively larger than an outer diameter of a previous dilator", and that "[i]t would have been obvious to one skilled in the art at the time the invention was made to construct the kit of Winslow . . . having a plurality of dilators in view of Smith, in order to dilate a passage with increased accuracy and reduced trauma". Additionally, the Office Action further asserts that "Orth et al. teaches (sic) a kit comprised in a container for holding the various kit components together, typically being a pouch, tray, box, tube, or the like", and that "[i]t would have been obvious to one skilled (sic) in the art at the time the invention was made to construct the kit of Winslow et al. in view of Orth in order to maintain sterility within the package". Furthermore, an assertion is made that "all the components of the claimed invention can be inherently assembled into a kit".

The Applicant notes that Winslow discloses an interbody fusion cage 200 which is inserted into an intervertebral disc space via a retractor instrument 10 including an axial sleeve 12 and a pair of retractor arms or tangs 20 extending from the sleeve 12. As set forth in column 9, lines 31-34 and Figure 11 of Winslow, "[u]pon insertion of retractor arms 20, the vertebral bodies V_1, V_2 are distracted whereby the retractor arms 20 become firmly lodged within the intervertebral space." The interbody fusion cage 200 is thereafter inserted through the sleeve 12 and into the intervertebral space.

Smith discloses a plurality of dilators 36, 39, 40 and 41. However, the dilators are used in procedures involving dilation of soft, stretchable tissue to increase the size of a passage through the soft tissue. More specifically, Smith discloses that the tissue dilators are used for "sequential percutaneous dilation of a tissue opening . . . while minimizing blood loss and without complication due to tearing of tissues", "to provide a sequential dilation device useful as part of procedures requiring access to the circulatory system such as a femoral bypass", and "to provide such a dilator system which can . . . be used for accessing the circulatory system" and which "permits atraumatic expansion of tissues and vessel walls with minimal blood loss". (Column 2, lines 18-39 and 61-64; Figures 5-7). Additionally, Smith discloses that "[t]he present invention fulfills a long recognized need in the medical field for a cannulation system which is adapted for femoral-to-femoral cardio-pulmonary bypass in a percutaneous fashion" and that "the present invention becomes even more significant in view of recent progress in percutaneous transluminal coronary angioplasty (PTCA) as a viable alternative to open-heart surgery. This new field depends on a viable method of percutaneous femoral cannulation which provides a high blood flow support system . . . In addition, the present invention reduces post-surgical scarring and damage to the vessel walls" and "sequential dilation device makes extracorporeal heart support a greatly simplified procedure". (Column 6, lines 28-54).

Although Smith discloses a plurality of tissue dilators, there is no teaching or suggestion whatsoever that the tissue dilator are sized and configured to incrementally increase a height of the intervertebral disc space, as recited in independent claims 16 and 21. To the contrary, the tissue dilators are used to dilate soft, stretchable tissue to increase the size of a passage through the soft tissue, and not to distract rigid vertebral bodies to incrementally increase a height of an intervertebral disc space. Additionally, the tissue dilators are specifically configured for use in association with the blood circulatory system to dilate an opening in a vessel wall. However, the plurality of dilators recited in independent claims 16 and 21 are sized and configured to act against bony structures (i.e., vertebral bodies) to incrementally increase a height of the intervertebral disc space, thereby requiring a dilator formed of a much harder and rigid material compared to the soft/flexible tissue dilators disclosed in Smith that are used in association with blood vessels. The flexibility and softness of the tissue dilators would prohibit use of these

components to distract an intervertebral disc space where much more rigid anatomical features are encountered.

Additionally, contrary to the assertion set forth in the Office Action, the Applicant submits that it would not have been obvious to one skilled in the art to provide a kit including the retractor 10 and interbody fusion cage 200 of Winslow with the tissue dilators of Smith to arrive at the surgical kits recited in independent claims 16 and 21. As indicated above, Winslow discloses a retractor 10 that is specifically configured to distract adjacent vertebrae apart via insertion of the retractor arms 20 into the intervertebral space. Since Winslow already discloses a specific type of instrument to distract the disc space, one skilled in the art would not provide additional instrumentation to provide sequential distraction of the intervertebral disc, such as the tissue dilators disclosed in Smith or the plurality of dilators recited in independent claims 16 and 21. Indeed, the addition of such instrumentation would be duplicative, unnecessary, and would result in increased cost without any benefit whatsoever. Additionally, Winslow discloses that "[e]ach retractor arm 20 has first and second vertebrae supporting surfaces 20a, 20b in general parallel relation to each other" and "[t]he height 'h' of each arm 20 (i.e., the distance between supporting surfaces 20a, 20b) corresponds to the height of the intended distraction distance" of the adjacent vertebrae. (Column 5, line 66 to column 6, line 6). As should be appreciated, once the retractor arms 20 are inserted into the intervertebral disc space and the disc space is distracted to the intended distraction height, there is no requirement to further distract the disc space. Accordingly, one of ordinary skill in the art would not supplement the retractor 10 of Winslow with a plurality of dilators to provide further distraction of the disc space, for to do so would be unnecessary and therefore superfluous.

Furthermore, since the tissue dilators of Smith are used to dilate soft, stretchable tissue, and are specifically configured for use in association with the vascular system to dilate an opening in a vessel wall, there would be no motivation or suggestion to combine the tissue dilators with an intervertebral spinal implant and/or other components and devices used in association with a spinal implantation procedure. As should be appreciated, one of ordinary skill in the art would not be motivated to use an intervertebral spinal implant in vascular procedures involving dilation of a tissue opening in a vessel wall. Accordingly, one skilled in the art would

be dissuaded from combining the tissue dilators of Smith with the distractor instrument 10 and interbody fusion cage 200 of Winslow to provide the surgical kit recited in independent claims 16 and 21.

Additionally, the Applicant notes that independent claims 16 and 21 do not merely recite a combination of components, but more specifically recite a particular combination of components that are combined to form a surgical kit. However, neither Winslow nor Smith disclose or suggest the concept of combining components in a self-contained surgical kit including an intervertebral spinal implant and a plurality of dilators that are configured to incrementally increase the height of an intervertebral disc space, as recited in independent claims 16 and 21. Additionally, independent claims 16 and dependent claims 22 and 34 further recite that the surgical kit components are contained within packaging to maintain the kit components in a sterilized condition. However, none of the references of record disclose the concept of providing an intervertebral spinal implant and a plurality of dilators within common packaging to provide a self-contained surgical kit for use in spinal implantation procedures. Additionally, while Orth appears to disclose a kit, Orth does not disclose or suggest containing the specific components recited in independent claims 16 and 21 in common packaging to provide a surgical kit in a sterilized condition for use in association with spinal implantation procedures.

Moreover, as set forth on page 3 of the Office Action, an assertion is made that "all of the components of the claimed invention can inherently be assembled into a kit." However, in order for an element to be inherently disclosed, it must "necessarily be present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." In re Robertson , 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citing Continental Can Co. v. Monsanto Co., 948 F2d 1264, 1268 (Fed. Cir. 1991)). Furthermore, inherency "may not be established by probabilities or possibilities . . . The mere fact that a certain thing may result from a given set of circumstances is not sufficient." Id. at 1951. Additionally, "[i]n relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the teachings of the applied prior art." Ex parte Levy, 17 USPQ2d 1461, 1464 (USPTO Bd. of Pat. App. and Interferences 1990) (emphasis in the original). It is respectfully submitted that

packaging each of the components recited in independent claims 16 and 21 in a self-contained surgical kit is not disclosed in the cited references so as to "necessarily be present in the thing described in the reference", and likewise does not necessarily flow from the teachings of the cited references. Additionally, the Office Action has not provided any basis in fact and/or technical reasoning supporting the inherency of packaging each of the components recited in independent claims 16 and 21 in a self-contained surgical kit. Indeed, the statement set forth in the Office Action regarding inherency is merely conclusory. Accordingly, a *prima facie* case of obviousness has not been established with regard to independent claims 16 and 21 for this additional reason as well.

For at least the reasons set forth above, the surgical kit recited in independent claims 16 and 21 is not disclosed, inherently or otherwise, by Winslow, Smith and Orth. Accordingly, the Applicant submits that independent claims 16 and 21 are patentable over the combined teachings of these references, and allowance of the same is respectfully requested.

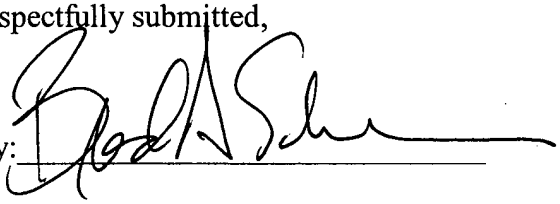
Additionally, claims 17-19 and 22-36 depend either directly or indirectly from independent claims 16 and 21, and are submitted to be patentable for at least the reasons supporting the patentability of their respective independent base claims. However, further reasons support the patentability of dependent claims 17-19 and 22-36. For example, claims 17 and 30 recite that the surgical kit further includes "a tool for delivering" the spinal implant through one of the dilators and into the intervertebral space, and claims 18 and 27 recite that the surgical kit further includes "a bone matrix material" to facilitate fusion within the intervertebral disc space. Additionally, claims 26, 28 and 35 recite that the surgical kit further includes "at least one guide needle configured to guide the distal end of the first dilator into the intervertebral disc space". Moreover, claims 31-33 recite that the surgical kit further includes third, fourth and fifth dilators, respectively. However, none of the references of record disclose or suggest the concept of packaging these additional components within the self-contained surgical kit recited in independent claims 16 and 21.

CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the Applicant's application is now in condition for allowance with pending claims 16-19 and 21-36.

Reconsideration of the subject application is respectfully requested. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

Respectfully submitted,

By: 

Brad A. Schepers
Reg. No. 45,431
Krieg DeVault LLP
One Indiana Square, Suite 2800
Indianapolis, Indiana 46204-2079
(317) 238-6334 (voice)
(317) 238-6371 (facsimile)